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FROM THE EDITOR'S MAILBAG

To the Editor:
I was disturbed to read your report of my comments made at the Food & Drug Law Institute Seminar on drug GMPs held in Washington April 2-3. This report appeared in the May 1979 "Industry Happenings" (page 110). Your reporter completely misquoted my opening remarks during the wrap-up session to the point that my integrity, responsibility and reliability have been impaired. I received telephone calls from clients and associates who were shocked at the quotation allegedly attributed to me.

What I said in my opening remarks at the wrap-up session was:

> "During these two-day briefing sessions on the Current GMP regulations, no one has commented on nor brought up the economic impact that these new regulations will have upon the industry. They will have an increased economic impact. To implement the requirements of these new regulations, there will be a need for capital expenditures for additional equipment and instrumentation plus an increase in personnel for validation procedures and for the additive documentation and administration called for. This economic increase will have an effect of increasing the manufacturing costs of the drug products by 4-10 percent depending upon the size of the company."

Anybody conversant in regulatory affairs knows that any agency of the government proposing any changes in any regulations are required by Executive Orders #11821 and 11949, by the Office of Management and Budget Circular #A-107, and for the FDA to be consistant with HEW guidelines to prepare and evaluate the potential economic impact that the changes in the proposed regulations may set forth. The FDA **did** prepare an economic impact report, which is mentioned in the preamble to the GMP regulations on page 45015 of the September 29, 1978 issue of the **Federal Register** and is available to anyone who requests a copy. I have a copy in my files. This report, basically part of the GMP regulations, does state that the new regulations will have an increased economic impact on the pharmaceutical industry but not a major economic impact as defined by the government criteria. With such knowledge, it would be totally irresponsible if I had made the statement you had erroneously reported in your May 1979 issue. For the record,

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In the battle over the safety of DES (a synthetic estrogen) it appears the women who claim to have been adversely affected by the drug taken during their mothers' pregnancy have won a skirmish in Michigan. In a decision announced in Lansing, Mich., the State Court of Appeals ruled two to one, that the 182 plaintiffs were entitled to sue the 16 drug manufacturers, a major source of contention in the battle. The agent was commonly administered in the 1940's and 1950's to prevent miscarriages. In subsequent tests, it was discovered to be ineffective for that purpose and in fact, was strongly linked to the formation of a benign vaginal abnormality called adenosis and in some women the drug turned out to be a predisessor to vagijnal cancer.

In the large group of plaintiffs, a majority was unable to named exactly which company produced the drug taken by their mothers, but at present, all 16 of the pharmaceutical firms will be held jointly responsible for the drug linked injuries.

A recent letter from the FDA Associate Deputy Commissioner for Regulatory Affairs, Willaim F. Randolf, to the CTFA, informed the organization that the federal agency has changed its policy with regards to metric labeling. The letter outlines the options a cosmetic manufacture how has in complying with requirements for label declaration. Declaration may be in terms of U.S. customary units (fluid ounces) only. A primary declaration in terms of US customary units accompanied by declaration in terms of metric units or vice versa is also permissable. Any questions relating to this current labeling specification should be directed to CTFA general counsel Steve McNamara at the Cosmetics Toiletries and Fragrances Association, 1133 Fifteenth St., Washington D.C., 20005.